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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

GP

Office Action Summary	**Application No.** 10/677,668	**Applicant(s)** MORRIS, GARY JAY	
	Examiner Nikolai A. Gishnock	**Art Unit** 3714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7-11,13-16,19-23,25-47,50,51,53 and 55-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7-11,13-16,19-23,25-47,50,51,53 and 55-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

In response to Applicant's remarks, filed 7/2/2007, claims 5, 6, 12, 17, 18, 24, 48, 49, 52, & 54 are cancelled. Claims 1-4, 7-11, 13-16, 19-23, 25-47, 50, 51, 53, & 55-57 are pending.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

    1. Determining the scope and contents of the prior art.
    2. Ascertaining the differences between the prior art and the claims at issue.
    3. Resolving the level of ordinary skill in the pertinent art.
    4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 2, 4, 7, 8, 10, 14-16, 19, 20, 23, 26, 28-30, 35-37, 39, 40, 44-47, 50, 51, 53, & 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morris et al. (US 7,021,940 B2), hereinafter known as Morris, in view of Gordon et al. (US 3,947,974), hereinafter known as Gordon.

4. Morris teaches an apparatus for simulating human blood pressure cycles and providing a tactile interface, comprising: an element to generate pressurized fluid, external to a pressure vessel (1:45; also Figure 1, Item 1); where the pressurized fluid is pneumatically conveyed to

the inside of the pressure vessel or chamber (bladder, 3:56-60), comprising at least one movable surface and distendable surface (6:32-36), whereby a human senses, through tactile contact with the pressure vessel, fluid pressure amplitudes within the pressure vessel (7:9-18); simulated human blood pressure levels maintained within the pressure vessel (7:41-54); where the simulated human blood pressure levels oscillate with a frequency equivalent of a human cardiac pulse rate (2:36-50); and a pressure sensor electronically senses pressure levels within the pressure vessel (via a comparator circuit) and provides pressure data feedback to an electronic control unit (processor, all at 7:41-8:3), where the apparatus is not used to measure an actual blood pressure of a human (manikin with simulated blood pressure and pulse, 2:57-59) [Claims 1, 4, 29, & 39]. What Morris fails to explicitly teach is where the electronic control unit controls pressure amplitude oscillations of the pressurized fluid inside the pressure vessel between simulated human systolic and diastolic blood pressure levels [Claim 1], and where the pressure sensor is in *pneumatic* contact with the pressurized fluid [Claim 1], as in the Applicant's Specification, page 4, lines 16-20, which defines contact as, "A fluid pressure sensor 130 senses the pressure level within the pressure vessel with moveable surface 120 and provides pressure data feedback to the electronic control unit 140. A manifold 135 pneumatically connects the fluid pressure control element 110, the pressure vessel with moveable surface 120, and the fluid pressure sensor 130". However, Gordon teaches a system for simulating human blood pressure (1:56-68), employing an electronic control assembly (6:41; see also Figure 1, Item 63). Gordon teaches that a mercury manometer indicator tube in a simulated sphygmomanometer is provided on the rear surface with a series of electrical contacts that are connected to the blood pressure electronic control assembly (6:45-49). Gordon further teaches that the electronic control assembly comprises a disease discriminating logic memory, which establishes appropriate blood pressure combinations in response to the input from the disease select system, and using 15 disease combinations, thirty contacts are provided to sense the systolic and diastolic parameters in the manometer tube (6:59-7:1). Gordon further teaches that the characteristic diastolic and systolic pressures for a particular disease may be selected by dialing a pre-assigned number in terms of units and tens on the two switches (7:25-30). The electronic control unit of Morris, which simulates blood pressure by opening and closing solenoid valve at a cyclic rate, simulating a pulse rate (Morris, 2:36-50) is understood to sense the systolic and diastolic pressures of a blood vessel in a body. Further, Gordon specifically implies human blood pressure by referring to a manikin of a cardiological patient (1:42-43). Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used Morris's electronic control unit to controls pressure amplitude oscillations of the pressurized fluid inside the pressure vessel between simulated human systolic and diastolic blood pressure levels, in the fashion of Gordon, in order to simulate a more realistic cardiological patient [Claims 1, 29, & 39]. Additionally, it is understood that the pressure sensor of Morris (Morris, Figure 7, Item 22) is touching, or *in contact with* the pressurized fluid within the pressure vessel (vessel simulating bladder, Morris, Figure 7, Item 401), as contact is commonly defined as "an act or state of touching, immediate proximity, or association", in the same fashion as series of electrical *contacts* in the mercury manometer are in contact with the pressurized fluid in Gordon (6:45-49). An obvious embodiment of the pressure sensor of Morris would be located in pneumatic contact with the pressurized fluid in the vessel simulating bladder, as taught by Gordon's electrical contacts, in the mercury manometer. In the embodiment of Morris, the device would indeed be operable because the sensor taught by Morris to be functional in a pressurized vessel (inflatable cuff, Morris, 7:49-54). Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have the pressure sensor of Morris in *pneumatic* contact with the pressurized fluid, as taught by Gordon, in order for invention to more realistically simulate the external appearance and function of a conventional clinical apparatus [Claims 1, 29, & 39].

5. Morris discloses where the fluid is a gas (3:56-60) [Claims 2, 30, & 40].

6. Morris discloses an electric solenoid controlled valve system connected to the pressure vessel (solenoid valves 403 & 503, 7:9-18 & 7:55-8:3) [Claim 8], which are inherently electromechanically actuated pressure regulators [Claim 7].

7. Morris discloses where the pressure vessel comprises an elastomeric hollow bulb (elastically deformable bladder) that can be held in a human hand (bladder is mounted to protrude from the interior of the manikin and into a simulated {external} umbilicus stub, which inherently could be gripped, 6:60-7:4; also Figure 7, Items 500 & 501), and internal pressure amplitudes of fluid within the bulb as sensed by human touch (7:9-18) [Claim 10].

8. Morris discloses where the pressure vessel is comprised of an elastic walled, closed tube whereby the cyclic, simulated blood pressure levels inside the tube are sensed by human gripping of the tube (silicone tube sealed at the distal end and mounted on the exterior surface of the arm of the manikin, where it inherently could be gripped by a human hand, 6:32-41) [Claim 14].

9. Morris discloses at least one user-operable control to select minimum and maximum limits of pressures within the pressure vessel to simulate systolic and diastolic blood pressure levels (blood pressure dial, 7:41-83; also Figure 6, Item 24) [Claim 15], and at least one user operable control to set a simulated cardiac pulse rate for the simulated human blood pressure cycles (pulse rate dial, 7:9-18; also Figure 6, Item 20) [Claim 16] and to set pressure excursion parameters within the pressure vessel [Claim 46], where the pressure excursion parameters are selected from the group consisting of simulated pulse rate, and simulated systolic and diastolic

pressure levels (7:9-18 & 7:41-8:3) [Claim 47]. Morris discloses a visual pressure level indicator including an analog display (pressure gage, 7:41-54) [Claim 35].

10. Morris teaches an apparatus for simulating normal and abnormal human blood pressure and providing a tactile interface, comprising: a pressure vessel containing pressurized fluid (bladder, 3:56-60), generated outside of the pressure vessel (1:45; also Figure 1, Item 1), the vessel having at least one movable surface and distendable surface (6:32-36), whereby a human senses, through touch, periodic fluid pressure amplitudes within the pressure vessel (7:9-18); simulated human blood pressure levels maintained within the pressure vessel (7:41-54); where the simulated human blood pressure amplitudes cycle between systolic and diastolic pressure levels with a frequency equivalent of a human cardiac pulse rate (2:36-50); and a visual indicator to display indicia which specify pressure amplitudes within the pressure vessel (pressure gage, 7:41-54). Morris further teaches simulating cyclic normal and abnormal fluid flow conditions within various fluid carrying body cavities, such as blood flow within a blood vessel (4:17-25), and specifically teaches a user operable electronic switch for toggling between simulating a normal activity of the lung, and a pneumothorax condition of the lung, which is defined as simulating where only one lung functions as a result of an abnormal condition such as a puncture or other defect (5:58-6:3; also in Figure 6, Item 17). What Morris fails to explicitly teach is a device to produce the periodic pressure amplitude cycles within the pressure vessel, the cycles comprising at least one abnormal human blood pressure amplitude cycle [Claims 19 & 36]. However, Gordon teaches a disease discriminating logic memory, which establishes appropriate blood pressure combinations in response to the input from the disease select system, and using 15 disease combinations, thirty contacts are provided to sense the systolic and diastolic parameters in the manometer tube (6:59-7:1). The body cavity and blood vessel fluid flow condition simulator of Morris would implement the disease blood pressure conditions

taught by Gordon. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have incorporated a device to produce the periodic pressure amplitude cycles within the pressure vessel, the cycles comprising at least one abnormal human blood pressure amplitude cycle, as taught by Gordon, in the blood pressure simulating apparatus of Morris, in order to certify the clinical diagnostic capabilities of both students and experienced physicians over a period of time, with an objective standard [Claims 19 & 36].

11. What Morris further fails to explicitly teach is where an electronic switch toggles between simulating the normal and abnormal blood pressure amplitude cycles [Claims 19, 36, & 50-53]. However, Gordon teaches that the characteristic diastolic and systolic pressures for a particular disease may be selected by dialing a pre-assigned number in terms of units and tens on the two switches (7:25-30), including "on" and "start" switches (Figure 5, Item 48). The switches of Gordon would be used to toggle between simulated normal and diseased blood pressure in the simulator of Morris. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have merely provided a switch to toggle between the normal and abnormal blood pressure amplitude cycles and pulse rates, in the same way as taught by Morris for toggling normal and abnormal lung functions, for the purpose of effecting a more simple and compact control unit that can simulate various blood flow conditions [Claim 19, 36, & 50-53].

12. Morris discloses where the fluid is a gas (3:56-60) [Claims 20 & 37].

13. Morris discloses where the pressure vessel comprises an elastomeric hollow bulb that can be held in a human hand (6:60-7:4; also Figure 7, Items 500 & 501), and internal pressure amplitudes of fluid within the bulb as sensed by human touch (7:9-18) [Claim 23].

14. Morris discloses where the pressure vessel is comprised of an elastic walled, closed tube, whereby the amplitude inside the tube is sensed by human touch (6:32-41) [Claim 26].

15. Morris discloses a visual indicator, comprising an analog pressure gage, which indicates the pressure level of the pressurized fluid (7:41-54) [Claims 28 & 56].

16. Morris discloses at least one user-operable control to set pressure excursion parameters within the pressure vessel [Claim 44], where the pressure excursion parameters are selected from the group consisting of simulated pulse rate, and simulated systolic and diastolic pressure levels (7:9-18 & 7:41-8:3) [Claim 45].

17. Claims 3, 21, 22, 31, 33, 38, & 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morris in view of Gordon, and further in view of Futcher et al. (US 5,722,413), hereinafter known as Futcher. Morris teaches all the features as demonstrated above in the rejections of claims 1, 19, 29, 36, & 39, including a pressurized fluid supply connected to a pressure vessel (bladder) via input tubing (3:29-36), for simulating cyclic blood pressure amplitudes. Morris teaches this pressurized fluid source may be a regulated air or oxygen source (4:40), which are gases. Morris also teaches using a pressure gage to measure simulated blood pressure (7:41-54). What Morris fails to teach is where this fluid source may comprise a substantially segregated mixture of gas and liquid [Claims 3, 21, 31, 38, & 41]. However, Futcher teaches a pressurized fluid which is a substantially segregated mixture of gas and liquid (air flows into the tube and through to the manometer, 4:1-7). The manometer contains liquid (Figure 1, Item 2), which forms a substantially segregated mixture with the air, due to their interaction in the manometer. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have substituted the liquid manometer of Futcher for the analog pressure gage of Morris, in order to determine the pressure inside the pressure vessel while substantially segregating the gas and liquid in the

fluid, for the purpose of increasing the accuracy of the pressure measurement by using a heavier, incompressible fluid during measurement [Claims 3, 21, 31, 38, & 41].

18. Morris further fails to teach where the pressurized fluid is generated by at least one manually operated pump. However, Futcher teaches a bulb that, when squeezed and then released, forces air into and out of a connector. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have substituted the pressurized fluid supply of Morris for the manual bulb pump of Futcher, in light of the teachings of Gordon, in order for a patient to better gauge the fluid flow to the bladder, and to provide a cheaper source of pressurized fluid than the compressed air or oxygen of Morris [Claims 22 & 33].

19. Claims 9, 13, 25, 27, 32, & 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morris, in view of Gordon, and further in view of Tumey et al. (US 5,991,654), hereinafter known as Tumey. Morris teaches all the features as demonstrated in the rejection of claims 1 & 29 above, including a pressurized fluid supply connected to a pressure vessel (bladder) via input tubing (3:29-36), for simulating cyclic blood pressure amplitudes. What Morris fails to teach is where the element to generate pressurized fluid is at least one electric powered pump [Claims 9 & 32]. However, Tumey teaches the use of an electric air compressor (a type of pump) connected to an air cuff (a pressure vessel) via a hose, for generating a pressurized fluid and causing pressure amplitudes within (3:58-4:6; also Figure 4, Item 46). Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have substituted the pressurized fluid supply of Morris for the electric powered pump of Tumey, in light of the teachings of Gordon, in order to provide a cheaper source of pressurized fluid than the compressed air or oxygen of Morris [Claims 9 & 32].

20. Morris also teaches a manikin having an elastically deformable bladder simulating an umbilical blood vessel (6:59-7:8), in which the realistic feel of blood flow can be felt by touch. Morris also discloses an inflatable cuff in communication with the electronic comparator of the electronic control unit processor for use as a pressure sensor (7:41-54; also Figure 7, Item 21) What Morris fails to teach is where the pressure vessel comprises an inflatable cuff whereby the periodic pressure amplitudes inside the cuff are sensed by human touch [Claims 13 & 25]. However, Tumey teaches the use of an air cuff that is periodically or cyclically inflated and deflated to apply periodic pressure to a patient's limb (8:9-41). Because the cuff is fastened to a patient, it is inherent that the pressure amplitudes would be sensed by human touch. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have substituted the air cuff of Tumey for the manikin with flexible bladder of Morris, in light of the teachings of Gordon, for the purpose of allowing the pressure vessel to be fastened onto a patient's limb, so that the patient can feel the pressure amplitudes without having to grip the vessel [Claims 13 & 25].

21. Morris teaches a visual indicator to display indicia, which specify pressure amplitudes within the pressure vessel (pressure gage, 7:41-54). What Morris further fails to teach is the indicator comprising an electronic digital display [Claims 27 & 34]. However, Tumey teaches a computer monitor that provides a visual aid to observe various output signals, such as cuff pressure (4:39-44) Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have substituted the electronic digital display of Tumey, for the pressure gage in the circulatory simulation of Morris, in light of the teachings of Gordon, in order to reduce the difficulty of accurately reading a dial gage [Claims 27 & 34].

22. Claims 11 & 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morris, in view of Gordon, as applied to claims 1 & 19 above, and further in view of Frazier (US 6,669,624), hereinafter known as Frazier. Morris teaches all the features as demonstrated in the rejections of claims 1 & 19 above, including an elastomeric hollow bulb (elastically deformable bladder) for tactile simulation of blood pressure by human touch (6:59-7:23). What Morris fails to explicitly teach is an incompressible, non-liquid member positioned within the second elastomeric hollow bulb such that substantial portions of the internal surfaces of the bulb are held in contact with the incompressible member by manually squeezing the bulb [Claims 11 & 55]. However, Frazier teaches a heart-assist pump comprising a flexible balloon catheter, inflated and deflated by gas pressure, with an incompressible lumens within the balloon for conveying gas to and from the balloon (6:7-28 and Figure 2, Items 8 and 14). The incompressible member taught by Frazier would be incorporated inside the pressure vessel of Morris, and aid in the uniform inflation and deflation of the pressure vessel. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have fabricated the pressure vessel as taught by Morris, with the incompressible member of Frazier, in light of the teachings of Gordon, in order to allow the bulb to withstand rapid cyclic inflation and deflation [Claims 11 & 55].

23. Claims 42 & 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin (US 4,773,865), hereinafter known as Baldwin, in view of Morris, and further in view of Rosendahl (US 6,606,907 B1), hereinafter known as Rosendahl. Baldwin teaches an apparatus for simulating human blood pressure and providing a tactile interface comprising: a first elastomeric hollow bulb (bulb syringe 62) to pressurize fluid by manual compression of the bulb; an elastomeric hollow tube (simulated femoral artery 52') pneumatically connected to the first

bulb through a bi-directional flow connection (tubes 52, 52', 54, & 56) such that the pressure in the second bulb is controlled by the amount of manual compression of the first bulb; the second elastomeric hollow bulb providing a tactile interface to a human subject where the human subject physically senses fluid pressure magnitudes internal to the second bulb by gripping with at least one hand (4:24-28; squeezing the bulb inherently provides the fluid pressure the student uses to feel the simulated pulse). What Baldwin fails to teach is a visual indicator to display indicia, which specifies pressure magnitudes within the second elastomeric hollow bulb [Claim 42]. However, Morris teaches a visual indicator to display indicia, which specify pressure amplitudes or magnitudes within the pressure vessel or elastomeric hollow bulb (pressure gage, 7:41-54). Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have connected a visual pressure indicator, as in Morris, to the simulated femoral artery of Baldwin, in order to facilitate locating the simulated artery by pressure or pulse [Claim 42].

24. What Baldwin fails to explicitly teach is abnormal blood pressure levels within the bulb. However, Morris further teaches simulating cyclic normal and abnormal fluid flow conditions within various fluid carrying body cavities, such as blood flow within a blood vessel (4:17-25). Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to simulate blood flow conditions, as taught by Morris, in the blood pressure simulator of Baldwin, for the purpose of providing a useful element in health care training, especially for emergency procedures [Claim 57].

25. What Baldwin and Morris further fail to explicitly teach is where the second bulb is a bulb, rather than being a tube, such that pressure-induced forces are amplified within the bulbs compared to within the conduit of smaller diameter than either the first or second bulb [Claims 42 & 57]. However, Rosendahl teaches a measurement apparatus for tactile gripping by a

human hand (hand, performing grasping, 1:27-28), which amplifies pressure induced forces (work and work rate, 1:44-47), using a bellows or bladder (2:1-11). The Applicant's specification at page 8, lines 14-22 state that, "It is understood that the concepts of the elastomeric hollow bulb described in this specification and appended claims are intended to be broad in scope and include all vessels having at least some non-fixed surface portion that can be used by humans to sense, through touch, pressure levels within such vessels. One function of the vessels with at least some non-fixed surface portion is to provide significant force amplification within the vessel compared to the force exerted on the walls of the relatively small diameter conduits comprising the manifold 135 and tubing 230 connecting the system components. The functions of elastomeric hollow bulbs described within this specification and appended claims may also be replaced with a *bellows apparatus* without loss of intended function of the invention", indicating that a bellows is an equivalent structure to the claimed bulb. Rosendahl teaches using a bulb or bellows to measure pressure and work (4:53-65). Because pressure is equal to force per unit area, and work is equal to the product of force in the direction of displacement, the bulb of Rosendahl causes a force amplification of a user's grip. Rosendahl further teaches that the volume of the pneumatic pipe linking the pneumatic reservoir and pressure-measuring means is trivial in relation to the volume of gas expelled from the reservoir (2:31-40). The volume of a pipe is a function of its diameter. The pneumatic linking pipe is thus understood to be of smaller than, or trivial compared to, the diameter of the bellows, or bulb. Rosendahl further teaches using a pneumatic reservoir in the form of a rubber bulb such as is used in a conventional sphygmomanometer (4:53-65). The feature of a first elastomeric bulb syringe for pressurizing the fluid manually and the principle of squeezing the device for the student uses to feel a simulated pulse, taught by Baldwin, would have the feature of providing a bellows (e.g. bulb) of larger diameter that the connecting tubing for the student to squeeze, as taught by Rosendahl.

Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have a second bulb or bellows, rather than being a tube, such that pressure-induced forces are amplified within the bulbs compared to within the conduit of smaller diameter than either the first or second bulb, as taught by Rosendahl, in the blood pressure demonstration system of Baldwin, in light of the teachings of Morris, in order to provide an elastic recoil pressure against which a user must work to grip the bulb [Claims 42 & 57].

26. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin, in view of Morris, Gordon, and Rosendahl, as in claim 42 above, and further in view of Frazier. Baldwin and Morris teach all the features as shown in the rejection of claim 42 above. What Baldwin and Morris fail to explicitly teach is an incompressible, non-liquid member positioned within the second elastomeric hollow bulb such that substantial portions of the internal surfaces of the bulb are held in contact with the incompressible member by manually squeezing the bulb [Claim 43]. However, Frazier teaches a heart-assist pump comprising a flexible balloon catheter, inflated and deflated by gas pressure, with an incompressible lumens within the balloon for conveying gas to and from the balloon (6:7-28 and Figure 2, Items 8 and 14). The incompressible member taught by Frazier would be incorporated inside the pressure vessels of either Baldwin or Morris, and aid in the uniform inflation and deflation of the pressure vessel. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have fabricated the pressure vessels as taught by Baldwin and Morris with the incompressible member of Frazier, in light of the teachings of Gordon, in order to allow the bulb to withstand rapid cyclic inflation and deflation [Claim 43].

Response to Arguments

27. Applicant's arguments with respect to claims 1, 2, 4, 7-8, 10, 14-16, 29, 39, & 57, filed 7/19/2007, see pages 17-18, have been considered but are moot in view of the new ground(s) of rejection.

28. Applicant's further arguments, filed 7/19/2007, see pages 18-27, have been fully considered but they are not persuasive. See below.

29. In response to applicant's argument that Morris fails to explicitly teach or imply periodic pressure amplitudes comprising at least one normal and at least one abnormal human blood pressure of claims 19 & 36, see page 19, Morris explicitly shows a system that simulates fluid flow conditions within various fluid-carrying body cavities, including blood flow within a blood vessel (4:17-25). Morris explicitly teaches simulating blood pressure (7:9-18). Morris further teaches his invention is an improvement (1:34-36) on simulations for practicing cardiopulmonary resuscitation (CPR) (1:16-24). CPR is provided to a human patient when conditions of abnormal heartbeat (and hence, blood pressure) occur within the patient. Therefore, the blood flow conditions being simulated in the invention of Morris, a medical training simulator (1:6-9), would imply that such conditions include at least one normal (resuscitated) blood pressure and at least on abnormal (in need of resuscitation) blood pressure. Thus, the applicant's argument is not persuasive.

30. In response to applicant's argument that Morris does not teach where an electronic switch toggles between simulating the normal and abnormal blood pressure amplitude cycles of claims 19 & 36, see pages 20-22, the examiner has not relied upon Morris to teach this feature in the present office action. Rather, Gordon teaches this feature (at least at 1:56-68). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must

be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Whether or not there is a teaching in the prior art of providing pulsation pressure amplitude control on the fly, or whether the pressure sensor of Morris directly or indirectly measures the contacted pressurized fluid, is irrelevant. In this case, Morris teaches a switch to toggle off and on a defect condition in a lung (5:58-6:3). Morris further teaches simulating various conditions within various fluid carrying body cavities of a single manikin, including a plurality of blood flow conditions in blood vessels (4:17-25). A proper determination was made that it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used a switch as was taught by Morris to toggle defects in the blood pressure, at least for the purpose of effecting a more simple and compact control unit. Thus, the applicant's argument is not persuasive.

31. In response to the applicant's argument that there is no reasonable expectation of success of adding a toggle switch to the cardiac simulation of Morris, obviousness does not require absolute predictability, however, at least some degree of predictability is required. *Evidence* showing there was no reasonable expectation of success may support a conclusion of nonobviousness. In re Rinehart, 531 F.2d 1048,189 USPQ 143 (CCPA 1976). See MPEP 2143.02. In this case, the applicant has not provided any evidence, only mere allegation, as to why Morris could not present a tactile feel of a pulse rate in a simulated blood vessel (2:36-50). Further, Morris teaches both a toggle switch to control normal and abnormal lung function, and normal and abnormal blood conditions. A proper determination was made that a person of ordinary skill in the art, at the time of invention, would have reasonably expected that rewiring, reconfiguring, or otherwise adding the user-operable, electronic pneumothorax switch of Morris to toggle between normal and abnormal blood pressure amplitude cycles, as shown above,

would be successful, in light of Morris's pulse rate and blood pressure adjusting dials (see Figure 6, Items 20 & 24), because electronically, a switch is simpler and cheaper to integrate into the invention than a dial. Thus, the applicant's arguments are unpersuasive.

32. Applicant's arguments with respect to claims 20, 23, 26, 28, 44, & 45, claim 52, claims 37 & 56, claim 50 and 51, claim 53, and claims 3, 21, 22, 31, 33, 38, & 41, see pages 22-23, amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. Thus, in view of the above reasons, the applicant's arguments for allowance of the claims are unpersuasive.

33. In response to the applicant's argument that Tumey teaches away from the applicant's invention, see pages 23-24, a prior art reference that "teaches away" from the claimed invention is a significant factor to be considered in determining obviousness; however, "the nature of the teaching is highly relevant and must be weighed in substance. A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). If the claims would have been obvious over the prior art because what the reference taught was useful for applicant's purpose, applicant did not distinguish the claims over the prior art, and applicant asserted no discovery beyond what was known to the art. Furthermore, "the prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed...." In re Fulton, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). See MPEP 2145(X)(C)(1). In this case, Morris teaches cycling the pressure in a vessel at the rate of a human cardiac pulse rate (2:36-50). The period of oscillation of Tumey is merely one embodiment; because Tumey discloses that the neural

network of a computer adjusts the inflation and deflation as required, for a predetermined period of time (8:9-41), Tumey does not teach away from the use of an electric-powered pump for generating a pressurized fluid or a pressure vessel being a pressurized cuff that is periodically or cyclically inflated, such that a patient can feel the pressure inside. The applicant's argument concerning one disclosed period of inflation is irrelevant. Thus the applicant's argument is unpersuasive.

34. In response to applicant's argument regarding claims 11, 43, & 55, see pages 24-25 & 27-28, that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case, the applicant states that member is not included to aid in rapid cyclic inflation end deflation in the Applicant's invention as the Examiner suggests, but rather to provide a substrate for the user of the device to press the bulb walls against to maintain a consistent feel (a compression goal) and to reduce the tendency for the user to randomly squeeze the bulb during the blood pressure simulation. In response, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art *cannot* be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In this case, the claims are obvious because Frazier teaches the same structural feature; an incompressible, non-liquid member positioned within the second elastomeric hollow bulb such that substantial portions of the internal surfaces of the bulb are held in contact with the incompressible member by manually

squeezing the bulb (6:7-28 and Figure 2, Items 8 and 14). It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have fabricated the pressure vessel as taught by Morris, with the incompressible member of Frazier, in light of the teachings of Gordon, in order to allow the bulb to withstand rapid cyclic inflation and deflation. Frazier's motivation to include the incompressible element to the elastomeric hollow bulb, which is different than the applicant's, is evidence of obviousness. Hence, the applicant's arguments are unpersuasive.

35. In response to applicant's argument that the tube to simulate a femoral artery 52' in Baldwin is very clearly buried deeply within the simulated leg 36 (see Fig. 6 of Baldwin) whereby it would not be physically possible for a human hand to grip this element as is a feature in Claim 42 of the Applicant's invention (similarly for arteries buried in the simulated neck), it is the examiner's understanding, based on Figures 1, 2, 5, & 6, that the simulated arteries of Baldwin are not buried deeply, and in fact, seem to be located near the surface. Nevertheless, Baldwin teaches that a student can feel the pulse, pressure, and position of the simulated vein (3:66-4:7), and the student is able to find each blood vessel and obtain sensory feedback (e.g. sense) that he or she is properly performing the medical technique (4:14-23). Thus Baldwin clearly indicates in prose that the student can locate the element. The term "grip" is understood to mean, "to grasp". It is inherent that for a student to feel the pulse of an artery, one must grip or grasp the limb or throat with fingers located on the artery. Furthermore, it is well-known and obvious to any medical doctor or nurse that both blood pressure and pulse can be felt in an artery. Thus, the applicant's argument is unconvincing.

36. Applicant's arguments, see page 26, filed 7/2/2007, with respect to claims 42 & 57 have been fully considered and are persuasive. The Examiner agrees that a larger bulb will experience force amplification over a smaller bulb, with the ratio of the larger bulb's surface area

to the smaller. However, upon further consideration, Rosendahl teaches using a bulb or bellows to measure pressure and work (4:53-65). Because pressure is equal to force per unit area, and work is equal to the product of force in the direction of displacement, the bulb of Rosendahl causes a force amplification of a user's grip. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have a second bulb or bellows, rather than being a tube, such that pressure-induced forces are amplified within the bulbs compared to within the conduit of smaller diameter than either the first or second bulb, as taught by Rosendahl, in the blood pressure demonstration system of Baldwin, in light of the teachings of Morris, in order to provide an elastic recoil pressure against which a user must work to grip the bulb.

Conclusion

37. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikolai A. Gishnock whose telephone number is 571-272-1420. The examiner can normally be reached on M-F 8:30a-5p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Xuan M. Thai can be reached on 571-272-7147. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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9/20/2007

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